

**UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK**

PFIZER INC.,

Plaintiff,

v.

UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES, and  
ALEX M. AZAR II, in his official capacity as  
Secretary of Health and Human Services, and  
UNITED STATES DEPARTMENT OF  
HEALTH AND HUMAN SERVICES  
OFFICE OF INSPECTOR GENERAL, and  
CHRISTI A. GRIMM, in her official capacity  
as Acting Inspector General in the Office of  
Inspector General for the U.S. Department of  
Health and Human Services,

Defendants.

Case No. 1:20-cv-4920-MKV

**BRIEF OF THE NATIONAL MINORITY QUALITY FORUM  
AS AMICUS CURIAE IN SUPPORT OF PLAINTIFF**

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## INTRODUCTION AND INTEREST OF THE *AMICUS CURIAE*<sup>1</sup>

Racial and ethnic minorities in the United States have suffered from disparate access to available health care resources for far too long. The grim results of these disparities are well known and widely documented, and yet do not—and should not—cease to shock our collective conscience. For instance, racial and ethnic minorities suffer from disproportionately high rates of chronic disease and premature death—Black men are over 50% more likely than whites to die prematurely from stroke<sup>2</sup>, Hispanic children and adolescents have the highest prevalence of obesity<sup>3</sup>, and Black women are two to six times more likely to die from complications of pregnancy than white women<sup>4</sup>. Some aspects of this disparity in health outcomes may arise from higher genetic propensity to certain diseases, but undeniably, a compounding factor is the fact that high-risk racial and ethnic populations lack equal access to health care.

Many factors have combined to deprive racial and ethnic minority populations of equitable access to health care. For example, the number of hospitals in urban areas dropped 46% from 1970 to 2010.<sup>5</sup> Minorities are underrepresented in drug treatment research programs.<sup>6</sup> Health care providers frequently lack the linguistic and cultural competence to serve minority

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<sup>1</sup> Undersigned counsel represent the amicus on a pro bono basis. No party's counsel authored this brief in whole or in part, and no party, its counsel, or any other person contributed money intended to fund preparation or submission of this brief. Cf. Fed. R. App. P. 29(a)(4)(E). All parties have consented to its filing.

<sup>2</sup> Office of Minority Health, U.S. Dep't of Health & Human Servs., *Stroke and African Americans*, <https://minorityhealth.hhs.gov/omh/browse.aspx?lvl=4&lvlid=28> (last visited Oct. 23, 2020).

<sup>3</sup> Nat'l Ctr. for Health Statistics, DHHS Publication No. 2016-1232, *Health, United States, 2015*, at 26 (2016); Alma D. Guerrero et al., *Racial and Ethnic Disparities in Early Childhood Obesity: Growth Trajectories in Body Mass Index*, 3 J. Racial & Ethnic Health Disparities 129 (2016); Carmen R. Isasi et al., *Health Issues in Hispanic/Latino Youth*, 4 J. Latinx Psychol. 67 (2016).

<sup>4</sup> Mary Beth Flanders-Stepans, *Alarming Racial Differences in Maternal Mortality*, 9 J. Perinatal Educ. 50 (2000).

<sup>5</sup> Nat'l Minority Quality Forum, *Solutions to Save Urban Hospitals: A Study of the Bayonne Model 1*, <https://www.nmqf.org/s/issuebrief4.pdf>.

<sup>6</sup> See, e.g., Nat'l Minority Quality Forum & Lupus Research All., *Addressing the Challenges of Clinical Research Participation Among Populations Disproportionately Impacted by Lupus: Findings and Recommendations of the Inaugural Lupus Multi-Cultural Engagement Partnership Meeting* (Dec. 2017), <https://www.nmqf.org/s/Lupus-MCEP-Report-FINAL.pdf>.

populations.<sup>7</sup> Thus, while it is clear that the issues surrounding health care access for minority communities do not begin or end with policies made by the U.S. Department of Health and Human Services, those policies can aggravate existing disparities, or they can begin to bring about much-needed change.

The Department's decision to characterize as a crime the provision of co-pay assistance to individuals who need help to afford treatment for a debilitating heart condition falls firmly into the former category. Equally unfortunate is the Department's rationale that desperately ill patients should not be provided copay assistance because of the costs that the Medicare system would incur if they were able to draw—as they could if they had more money—on Medicare to pay the balance of the cost for the drug. That rationale is one piece of a larger story in which the Department has failed to pay sufficient regard to the health care access needs of minority individuals, minority families, and minority communities.

The National Minority Quality Forum (“NMQF” or “the Forum”) is a nonprofit, nonpartisan research and educational organization dedicated to ensuring that high-risk racial and ethnic populations and communities receive optimal health care. NMQF integrates data and expertise in support of initiatives to eliminate health disparities that affect disadvantaged groups. Over the years, NMQF has focused primarily on effecting change through policy and organizing. For example, NMQF has hosted discussions regarding diversity in the health care workforce, organized community health clinics, and facilitated summits throughout the country to provide youth with mentorship, leadership training, and resources to make positive changes in their

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<sup>7</sup> See Nat'l Acads. of Scis., Eng'g, & Med., *Communities in Action: Pathways to Health Equity* 138 (2017) (“[D]ata do exist that indicate that behavioral and attitudinal elements of cultural competence facilitate higher-quality relationships between physicians and patients.” (citation omitted)).

communities<sup>8</sup>. NMQF's preferred method of effecting change is written advocacy, intended for a general audience, and focused on exposing various aspects of the large-scale disadvantages of inadequate access to optimal health care. For example, the Forum has published articles revealing the lack of adequate proper access to dental care for low-income and Medicare beneficiaries<sup>9</sup> and explaining how out-of-pocket payments for the fixed-dose combination of Hydralazine and Isosorbide Dinitrate (BiDil) negatively affect Black populations specifically.<sup>10</sup>

In this case, the Forum has determined—for the first time—to engage in courtroom advocacy. That decision reflects the importance of this case for the issues that are NMQF's focus. Approximately 100,000 individuals suffer from ATTR-CM, a disease that in certain hereditary forms disproportionately afflicts Black men. Without the Court's intervention, many will have to forego treatment that could meaningfully prolong their lives, purely because they cannot afford the co-pays necessary for Medicare to pick up the rest of the tab, and because the government will bar manufacturers from assisting with those co-pays. This amounts to a triple-blow for Black communities and Black families. First, their husbands, sons, and fathers are more likely to suffer from hereditary ATTR-CM. Second, because relatively few people in the population as a whole suffer from ATTR-CM, the costs of developing treatments are high, and the resulting price tag and co-pays for the drugs are high. And, third, the effects of the persistent wealth gap then come into play—Black families have less wealth than majority families with

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<sup>8</sup> Nat'l Minority Quality Forum, *2019 Annual Report* 1, 4, 14, <https://www.nmqf.org/s/NMQF-2019-Annual-Report.pdf>.

<sup>9</sup> Nat'l Minority Quality Forum, *Reassessing the Dental Care Paradigm: A National Minority Quality Forum White Paper* (Nov. 2015), <https://www.nmqf.org/s/Reassessing-the-Dental-Care-Paradigm.pdf>.

<sup>10</sup> Nat'l Minority Quality Forum, *Out-of-Pocket Payments for the Fixed-Dose Combination of Hydralazine and Isosorbide Dinitrate (BiDil)* (Mar. 8, 2017), <https://www.nmqf.org/nmqf-publications/out-of-pocket-payments-for-the-fixed-dose-combination-of-hydralazine-and-isosorbide-dinitrate-bidil>.



comparable levels of income, and are thus less likely to be able to afford to pay large co-pays out of pocket, especially across multiple years.<sup>11</sup>

Given these sources of structural inequality, the government’s overbroad construction of the Anti-Kickback Statute (AKS) is likely to exacerbate disparities in access to medical care by denying minority individuals private copay assistance and, by extension, denying them access to Medicare benefits that would be theirs if they could afford the co-pay. That approach to the AKS is neither wise nor equitable—as Pfizer aptly describes, it amounts to providing “*greater* benefits to individuals the *wealthier* they are.”<sup>12</sup> That is the opposite of what Congress intended when it created Medicare, and more recently, when it directed the Department to avoid the disparate treatment of minorities in the provision of health care benefits. There is simply no sound reason to treat the AKS as requiring, or permitting, that dramatically inequitable result.

## ARGUMENT

### **I. HHS has a responsibility to ensure that program beneficiaries from historically disadvantaged communities enjoy equal access to Medicare benefits.**

As originally enacted, the Medicare statute had a deceptively modest statement of purpose—“[t]o provide a hospital insurance program for the aged under the Social Security Act with a supplementary medical benefits program and an expanded program of medical assistance.” Social Security Amendments of 1965, Pub. L. No. 89-97, 79 Stat. 286. As it exists today, Medicare has grown to “provide health insurance for nearly 60 million aged or disabled Americans, nearly one-fifth of the Nation’s population.” *Azar v. Allina Health Servs.*, 139 S. Ct. 1804, 1808 (2019). The scope of the program is wide, providing access to life-saving treatments for “*all* elderly, as well as the disabled.” *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1105

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<sup>11</sup> Alexandre Tanzi, *Five Charts That Show the Extent of the Black Wealth Gap in U.S.*, Bloomberg (July 18, 2020), <https://www.bloomberg.com/news/articles/2020-07-18/five-charts-that-show-the-extent-of-the-black-wealth-gap-in-u-s>.

<sup>12</sup> Mot. Summ. J. 3.

(D.C. Cir. 2014) (emphasis added). Given the inclusive set of beneficiaries for whom Medicare is intended, and given that “[o]ne way or another, Medicare touches the lives of nearly all Americans,” 139 S. Ct. at 1808, the need to ensure equality of access to care for all sectors of the beneficiary population is a paramount one.<sup>13</sup>

For two reasons, a concern for equal access should be front and center in this case, in which the government is attempting to defend its decision to block Pfizer from providing financial assistance to patients who otherwise could not afford the Medicare co-pays for a Pfizer-made drug designed to treat ATTR-CM. First, a sustained body of research—including publications from the Department’s Center for Medicare & Medicaid Services—reveals that as a factual matter, members of minority groups face significant disparities in access to and quality of care received through Medicare. Second, the agency has an obligation, as a matter of law and stated policy, to eliminate these disparities. And yet the government’s approach to interpreting the AKS displays no evident concern for equality of access, and to the contrary, would serve to perpetuate unwarranted disparities.

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<sup>13</sup> Indeed, Medicare (and Medicaid) have historically been used as instruments for enforcing racial equality. For instance, in 1969 the IRS issued Revenue Ruling 69-545, which developed what is still known as the “community benefit standard” for determining whether a hospital qualified as a charitable organization. Importantly, that standard required hospitals seeking to avail themselves of the exemption to “operat[e] an emergency room open to all persons” and “provid[e] hospital care for *all* those persons in the community able to pay the cost thereof either directly or through third party reimbursement.” Rev. Rul. 69-545, 1969-2 C.B. 11 (emphasis added). The ruling also makes clear that “able to pay” included payment through Medicare. *Id.* In other words, the combination of Medicare and the tax laws opened the door for eligible beneficiaries who were members of racial and ethnic minority groups to receive care on an equal basis. *See also* Internal Revenue Serv., *Charitable Hospitals - General Requirements for Tax-Exemption Under Section 501(c)(3)*, <https://www.irs.gov/charities-non-profits/charitable-hospitals-general-requirements-for-tax-exemption-under-section-501c3#:~:text=a%20private%20interest,Community%20Benefit%20Standard,charitable%20purpose%20of%20promoting%20health> (last updated Sept. 19, 2020) (“Once a determination is made that a particular patient is covered by health insurance, governmental program or otherwise has sufficient resources to pay for health care, and the hospital has the available space and can provide the appropriate medical services, the patient should be admitted to the hospital in a nondiscriminatory manner.”).

**A. Minority individuals and families are significant contributors to Medicare, but lack equal access to program benefits.**

Research repeatedly demonstrates that Medicare beneficiaries belonging to minority groups consistently lag behind white counterparts in terms of access to quality healthcare services. In fact, the Department published a study just last year, concluding that minority Medicare beneficiaries—across multiple racial and ethnic groups, including Black beneficiaries—faced substantial disparities in quality of care according to a wide range of patient-reported and clinical measures. *See* Office of Minority Health, Ctrs. for Medicare & Medicaid Servs., *Racial, Ethnic, and Gender Disparities in Health Care in Medicare Advantage*, at vi–vii (Apr. 2019), <https://www.cms.gov/About-CMS/Agency-Information/OMH/Downloads/2019-National-Level-Results-by-Race-Ethnicity-and-Gender.pdf> (noting that “Black and Hispanic beneficiaries received worse clinical care than White beneficiaries on a large portion of the clinical care measures examined”). Studies investigating the presence and causes of these disparities stretch back many years and—notably—consistently feature disparities in prescription drug access. Jennifer Schore et al., *Racial Disparities in Prescription Drug Use Among Dually Eligible Beneficiaries*, 25 *Health Care Financing Rev.* 77, 77–79 (2003), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194810/pdf/hcfr-25-2-077.pdf> (noting multiple studies demonstrating disparities in prescription drug use among Medicare beneficiaries, and observing that “members of racial minorities are less likely than those of non-minorities to receive appropriate medications for cardiovascular disease and AIDS”). These disparities include access to medications for cardiovascular disease, U.S. Gen. Accounting Office, GAO-03-862R, *Health Care: Approaches to Address Racial and Ethnic Disparities* 10–11 (2003) (noting racial and ethnic disparities in “appropriate medication” and “procedures” relating to cardiovascular disease), and are partially due to disparities in the ability to afford medications. As one study

reports, “[e]lderly black Medicare beneficiaries are more than twice as likely as white beneficiaries to not have supplemental insurance and to not fill prescriptions because they cannot afford them.” Schore, *supra*, at 77; *see also* Becky Briesacher et al., *Racial and Ethnic Disparities in Prescription Coverage and Medication Use*, 25 Health Care Financing Rev. 63, 63–64, 73–74 (2003), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4194807/pdf/hcfr-25-2-063.pdf>; Marie Reed et al., Ctr. for Studying Health Sys. Change, *Unequal Access: African-American Medicare Beneficiaries and the Prescription Drug Gap* 1–2 (July 2003), <http://www.hschange.org/CONTENT/586/586.pdf> (noting that “[t]he different pattern of supplemental coverage for elderly black and white Medicare beneficiaries helps to explain the prescription drug access gap between blacks and whites” and “[t]he lower incomes of older African Americans partially explain why they are less likely than whites to fill all of their prescriptions”). There is therefore no doubt that racial and ethnic disparities—including disparities in access to prescription medications—represent a problem with identifiable causes, and that the problem and its causes are known to HHS and related agencies.

**B. Congress and HHS have acknowledged these disparities and the agency’s obligation to address those disparities at an operational level.**

The agency’s obligation to avoid perpetuating racial and ethnic disparities in access to Medicare benefits derives from at least three sources.

*First*, Congress itself has spoken on the issue. The Patient Protection and Affordable Care Act, enacted in 2010, provides that “an individual shall not, on the ground prohibited under title VI of the Civil Rights Act of 1964 . . . be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance [including Medicare Part D] or under any program or activity that is administered by an Executive Agency or any entity established under this title (or

amendments).” 42 U.S.C. § 18116. Importantly, Title VI—the enforcement mechanisms for which are also incorporated into the Patient Protection and Affordable Care Act, *id.*—“reaches unintentional, disparate-impact discrimination as well as deliberate racial discrimination.” *Guardians Ass’n v. Civil Serv. Comm’n*, 463 U.S. 582, 593 (1983) (plurality opinion); 45 C.F.R. § 80.3(b)(2) (effectuating Title VI and forbidding “criteria or methods of administration” that produce disparate impact discrimination). This provision is a natural extension of Medicare’s promise to provide life-saving treatments and medications to “*all* elderly, and the disabled,” and underscores that the law requires more than that Medicare policies be neutral on their face. In end effect too, Medicare policies must work equitably, just like all other governmental policies subject to Title VI. *See, e.g., Lau v. Nichols*, 414 U.S. 563, 566 (1974) (noting that under Title VI “there is no equality of treatment merely by providing students with the same facilities, textbooks, teachers, and curriculum” where those students “do not understand English,” since “those who do not understand English are certain to find their classroom experiences wholly incomprehensible and in no way meaningful”), *abrogated on other grounds by Alexander v. Sandoval*, 532 U.S. 275 (2001). It follows that agency policies that serve to heighten racial or ethnic disparities in beneficiary access to quality medical care are legally suspect, just as they are morally and ethically problematic.

*Second*, HHS’s own description of its goals highlights the importance of ensuring equal access to Medicare benefits across all members of the beneficiary population. In 2011, HHS published the HHS Action Plan to Reduce Racial and Ethnic Disparities. That document expressed the Department’s commitment to “continuously assessing the impact of all policies and programs on racial and ethnic health disparities” and sought to explain how “the Department can leverage” the Affordable Care Act and other initiatives “in its effort to reduce racial and

ethnic health disparities.” U.S. Dep’t of Health & Human Servs., *HHS Action Plan to Reduce Racial and Ethnic Health Disparities* 1, 7 (Apr. 2011), <https://aspe.hhs.gov/system/files/pdf/206166/DisparitiesActionPlan.pdf>.

Finally, the HHS OIG itself has adopted a policy posture that rightfully places it at odds with decisions or actions that perpetuate or exacerbate racial and ethnic health disparities. Thus, OIG’s strategic plan for 2020–2025 describes one of its primary goals as to “promote quality, safety, and value in HHS programs,” notes that those programs “provide critical services to diverse populations,” and commits OIG “to providing oversight that helps HHS improve its programs and ensure that eligible beneficiaries receive appropriate services.” Office of Inspector Gen., U.S. Dep’t of Health & Human Servs., *HHS-OIG Strategic Plan 2020–2025*, at 12, <https://oig.hhs.gov/media/documents/OIG-Strategic-Plan-2020-2025.pdf>. Similarly, its mission statement explains its role as “provid[ing] objective oversight to promote the economy, efficiency, effectiveness, and integrity of HHS programs, as well as the health and welfare of the people they serve.” *Id.* at 3. Such goals are fundamentally inconsistent with an approach that fails to attend to disproportionate and negative effects on the ability of minority populations to access care.

## **II. HHS has historically made policy decisions inconsistent with the needs of disadvantaged communities.**

OIG’s rejection of Pfizer’s proposals is just the latest example of how HHS has made coverage and other program decisions that work at cross purposes with the need to ensure equal access to medical care for historically disadvantaged communities. The Black community in particular has borne the brunt of these shortcomings. In addition to tafamidis, which combats ATTR-CM arising in a hereditary form that primarily afflicts Black men, HHS has discouraged doctors from prescribing BiDil, a drug proven effective at treating heart failure in Black people.

Heart failure is a condition in which the heart is unable to pump enough blood to meet the body's demands. Black people face a heightened risk of heart failure, in part because high blood pressure and diabetes are more common among them and because, some scientists suspect, they may have lower levels of nitric oxide.<sup>14</sup> BiDil represents a significant medical advance for Black people in particular because the most effective drugs for combatting heart failure in the general population—angiotensin-converting enzyme (ACE) inhibitors—have been less effective for Black people, for reasons that are not yet fully understood.<sup>15</sup> BiDil is the result of a search for drugs that would address this effectiveness gap. The study that supported BiDil's FDA approval shows a 43% improvement in survival and a 33% reduction in first-time hospitalizations for heart failure compared to a treatment of a placebo and standard therapy.<sup>16</sup>

Instead of promoting this breakthrough medication, HHS discouraged doctors' prescriptions by encouraging Medicare Part D insurers to exclude BiDil from their formularies and by encouraging generic substitution of an unproven combination of drugs.<sup>17</sup> Medicaid programs and private insurers followed suit and imposed similar reimbursement limitations for BiDil, to the detriment of African-American patients who would benefit enormously from increased access to BiDil.<sup>18</sup>

For BiDil, like tafamidis, HHS staked its position on the high cost of the drug. That stance made no sense as a matter of policy because it failed to take account of cost savings that patients derive from taking a more effective medication. For example, economic analysis

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<sup>14</sup> *Heart Failure Is Different for African Americans, Find Out Why*, Arbor Pharm., LLC, <https://www.bidil.com/about-heart-failure/african-americans> (last visited Oct. 23, 2020).

<sup>15</sup> Letter from Daniel J. Popeo & Richard A. Samp, Wash. Legal Found., to Kerry N. Weems, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs., U.S. Dep't of Health & Human Servs., Re: Petition to Revise CMS Reimbursement Policies Regarding BiDil®, at 3 (Aug. 7, 2008).

<sup>16</sup> *Id.* at 3–4 (citing Anne L. Taylor et al., *Combination of Isosorbide Dinitrate and Hydralazine in Blacks with Heart Failure*, 351 N. Eng. J. Med. 2049 (2004)).

<sup>17</sup> *Id.* at 6.

<sup>18</sup> *Id.*

published in December 2005 shows that prescribing BiDil to Black heart failure patients as an add-on to standard therapies resulted in many fewer medical expenditures than when it was not prescribed.<sup>19</sup> Moreover, a myopic focus on price will have the end effect of exacerbating disparities in access to medical care because it ignores the reality that drugs that serve a minority of patients can be expensive to research on the front end and difficult to affordably price on the back end because of smaller user pools. Had the agency focused instead on the enormous heart-health benefits that BiDil could provide to a minority population that has historically received less than its fair share of Medicare expenditures, it appears very likely that the decision would have been different. One hopes that the Department might have learned its lesson from BiDil. But by all appearances, it is instead determined to commit the same fundamental error here.

**III. HHS is again failing to ensure equal access to tafamidis for the treatment of ATTR-CM—and in fact is blocking access to tafamidis.**

Once more, HHS has failed to ensure equal access to vital medication for a needy minority in the name of incentivizing lower costs (and, here, the supposed need to prevent illegal kickbacks). However, for the reasons already explained, the agency's single-minded focus on cost is flawed. And for reasons that Pfizer extensively articulates in the memorandum supporting its motion for summary judgment, the agency's interpretation is neither compelled by nor permitted under the law. *See generally* Mot. Summ. J. The agency's advisory opinion rejecting Pfizer's proposal at bottom reflects a policy approach that fails to sufficiently weigh the well-being of ailing patients, many of them Black, when considering practices that might result in increased expenditures by the agency.

Preventing Pfizer from providing financial assistance to Medicare beneficiaries in need of tafamidis will have enormous human consequences given the size and vulnerability of the

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<sup>19</sup> *Id.* at 7 (citing Derek C. Angus et al., *Cost-Effectiveness of Fixed-Dose Combination of Isosorbide Dinitrate and Hydralazine Therapy for Blacks with Heart Failure*, 112 *Circulation* 3745 (2005)).



population affected and given the grim prognosis for patients who, because of price, have been forced to live without the drug. The American Heart Association characterizes ATTR-CM as an “underdiagnosed and potentially fatal disease.”<sup>20</sup> The disease affects approximately 100,000 to 150,000 Americans (Compl. ¶ 3) and primarily impacts the elderly in its non-hereditary form, wild-type ATTR-CM.<sup>21</sup> However, hereditary ATTR-CM is more commonly found in Blacks in the United States with symptoms that may begin as early as age 20 or as late as age 80.<sup>22</sup> Black men, particularly older ones, have a higher risk of developing the disease from a hereditary mutation.<sup>23</sup> No cure exists for ATTR-CM, and untreated patients can expect to live on average 2 to 3.5 years after diagnosis. Compl. ¶ 3. Given that tafamidis is the only proven drug on the market, affordable access to this medication through programs like those proposed by Pfizer are a matter of life and death for diagnosed patients. OIG’s decision to characterize Pfizer’s proposed financial assistance to Medicare beneficiaries as a criminal act is inconsistent with the agency’s obligations to ensure equitable program access and to safeguard equally the wellbeing of all of its beneficiaries.

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<sup>20</sup> Am. Heart Ass’n, *What is Transthyretin Amyloid Cardiomyopathy (ATTR-CM)?* 1 (2019), [https://www.heart.org/-/media/files/health-topics/answers-by-heart/abh\\_what-is-attrcm\\_v2\\_a](https://www.heart.org/-/media/files/health-topics/answers-by-heart/abh_what-is-attrcm_v2_a).

<sup>21</sup> *Id.*

<sup>22</sup> *Id.* at 1–2.

<sup>23</sup> *Id.* at 2.

## CONCLUSION

For the foregoing reasons, the Court should reject the government's conclusion that it is a crime for a manufacturer to offer copay assistance to an individual in need of lifesaving treatment, and thereby eliminate one more barrier that minority patients must overcome to obtain vital medical care.

Respectfully submitted,

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### **CERTIFICATE OF COMPLIANCE**

Pursuant to part II.D of this Court's individual practices, I certify that the foregoing brief (i) contains 3,882 words, excluding the cover page, Table of Contents, Table of Authorities, and signature block, as determined by the word-count feature of Microsoft Word; and (ii) complies with the Court's formatting rules.

Dated: January 8, 2021

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